

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



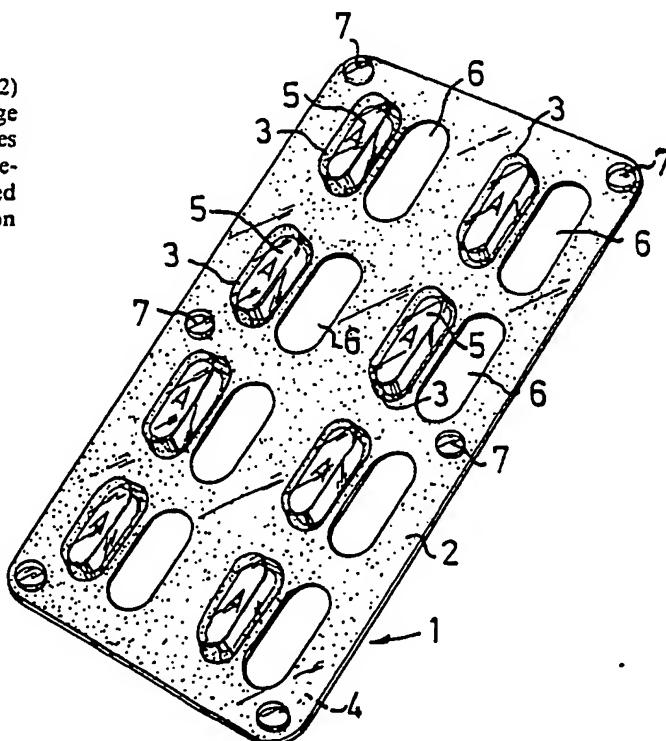
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>4</sup> :	A1	(11) International Publication Number: WO 88/02342 (43) International Publication Date: 7 April 1988 (07.04.88)
B65D 85/56		
(21) International Application Number:	PCT/SE87/00430	(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BG, BJ (OAPI patent), BR, CF (OAPI patent), CG (OAPI patent), CH, CH (Eu- ropean patent), CM (OAPI patent), DE, DE (Euro- pean patent), DK, FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (Euro- pean patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI pa- tent), SU, TD (OAPI patent), TG (OAPI patent), US.
(22) International Filing Date:	24 September 1987 (24.09.87)	
(31) Priority Application Number:	8604060-7	
(32) Priority Date:	25 September 1986 (25.09.86)	
(33) Priority Country:	SE	
(71) Applicant ( <i>for all designated States except US</i> ): ASTRA LÄKEMEDEL AKTIEBOLAG [SE/SE]; S-151 85 Södertälje (SE).		Published <i>With international search report. In English translation (filed in Swedish).</i>
(72) Inventor; and		
(75) Inventor/Applicant ( <i>for US only</i> ) : EEK, Arne, Torsten [SE/SE]; Villagatan 11, S-150 13 Trosa (SE).		
(74) Agents: MIKSCHÉ, Gerhard et al.; AB Astra, Patent- och Varumärkesavdelningen, S-151 85 Södertälje (SE).		

(54) Title: A DRUG PACK

## (57) Abstract

A drug pack (1) comprising a first card (2) provided with blisters (3) for tablets or other dosage units and a breakable underfoil. The card has holes arranged thus that through the holes blisters (9) belonging to a second drug pack may be introduced from the lower side of the first card to the formation of a combination pack.



A drug packTechnical field

5      The present invention is related to a novel drug pack, in general with the same basic construction as the tablet cards or "blister packs" which today are in extensive use. These consist usually of a card of plastic material which one side thereof is provided with a number of blisters for receiving therein a tablet and which on the other side thereof has a  
10     metal foil attached to the card, which foil seals the underside of the blisters. A tablet may be released by depressing the blister thus that the tablet breaks the foil.

Background of the invention and state of the art

15     In many instances it is necessary or desirable to treat a patient with two or more drugs, i.e. two or more active substances. These may be two or more substances which are used in the treatment of the same disease condition, or which are used in the treatment of different disease  
20     conditions. In the former case the substances may be substances having mutually complementary or synergistic effect. In the latter case the effects of the respective substances are often unrelated to each other. Intermediate forms occur where there is a varying degree of connection between different disease conditions and the effects of the drugs. An  
25     example of treatment of the same disease condition is the treatment of hypertension where substances with a direct activity on heart and vessels, such as beta blockers and calcium antagonists, may be used in combination with each other and with diuretics. Another example is treatment of pain where different analgesics, sedatives and muscle  
30     relaxants may be combined.

It is wellknown to provide drugs as a combination preparation wherein each dosage unit e.g. tablet contains a plurality of active substances. Combination preparations are however frequently connected with

limitations and drawbacks which causes then often not to provide the best possible treatment. A significant problem is the insufficient flexibility of combination preparations. Different patients may require different combinations of substances or different dosages of the various substances. Furthermore, the effect and duration of the various substances may be so different that simultaneous administration at each dosage time is not desirable. Finally, a substance may be indicated for supply several times per day while another substance is indicated for administration once a day, e.g. at bedtime.

10

Where thus combination preparations will not be used, one is today reduced to prescribing two or more drugs from different packages to the patient. It is well known that this implies difficulties in achieving the desired treatment. The patient has often difficulties in understanding which drugs are to be taken at which times and additionally often forgets instructions given. One has tried to remedy such problems by providing boxes with rows and columns of compartments wherein tablets for different times and days may be placed. This however, requires a time-consuming dispensing of single tablets which has to be done by nursing staff, the patient himself or herself or by relatives.

DE 2 103 694, GB 2 079 250 and US 4 254 871 are examples of designs which are intended to facilitate the handling of dosage units of drugs. 25 All however, require supply of a separate holder, base plate or frame in which dosage packs are placed. Further, they do not give any solution to the special problem of ensuring concurrent administration of two or more drugs at each dosage occasion.

30

The present invention has the purpose of providing a drug pack which enables simplified and safer treatment with two or more drugs which allows for a high degree of flexibility for different combinations and dose regimens and which does not require special holders or the like for dosage units or packs thereof.

Description of the invention

The present invention is thus related to a drug pack comprising a first card which on the upper side thereof is provided with a number of blisters for receiving therein drug dosage units, such as tablets or capsules, and which on the lower side thereof has a breakable underfoil attached thereto, through which dosage units may be released. The drug pack is characterized in that the first card has a number of openings arranged thus that blisters belonging to a second drug pack may be introduced through the openings from the lower side of the first card to the formation of a combination pack, wherein the second drug pack comprises a second card provided with such blisters, openings corresponding to the blisters of the first card and a second underfoil.

15 The invention enables the doctor, when treatment with a plurality of drugs is desired, to prescribe dispensing to the patient a combination pack assembled from two or more packs. In wholesale the pack is intended usually to be provided separately, which makes it possible when desired to provide the pack separately to the patient when treatment with a plurality of drugs is not intended.

20 A functioning pack of the invention can be made with an unbroken underfoil under the openings of the card, whereby, on assembling of two cards, the underfoil of the upper card is broken by the blisters of the lower card and whereby, on release of a dosage unit, the underfoil of the lower card is broken at the same time as the underfoil of the upper card is broken. It is however, preferred to construct the pack thus that the openings in the card extend through the underfoil as well, which will facilitate the assembling of packs and the releasing of dosage units.

25 30 35 According to a preferred embodiment of the invention each opening in the first card is located at a shorter distance from one blister than from other blisters in said first card. On assembling two cards, blisters from the first and the second cards will be located adjacent to each other in pairs, which makes it evident to the patient that the dosage units therein are to be taken out at the same time, preferably by simultaneous depression of the two blisters.

Preferably the pack is provided with attachment means for attachment of the first card to the second card. These attachment means are preferably designed as snap locks, for example in the form of tiny blisters on one card which may be introduced into holes or blisters on the second card and be locked therein. In the alternative it is preferred to design the attachment means as an adhesive material which is coated on or which on assembling of two packs is brought into contact with the underfoil of the first card and which will adhere to the underfoil and to the upper side of the second card. Thus the adhesive material may for example comprise strips of tape with adhesive compound on both sides; suitably provided with a releasable protective sheet, said strips being placed on areas of the underfoil which are not occupied by blisters or holes in the card. It is also possible to shape the blisters which are to receive the drug in such manner that the blisters of the lower card will lock into the holes of the upper card. Alternative attachment means may be loose buttons or pins which may be used for assembling the cards through holes therein, or rails that may be slipped over the edges of the assembled cards. Such buttons or rails are suitably packaged together with the pack. It is also possible to provide a simple apparatus to be used in the pharmacy for assembling two cards.

A combination pack comprising a first and a second drug pack as described above is a further aspect of the invention. A such combination pack is thus prepared in the pharmacy, but it is not out of the question for especially frequent combinations for combination packs to be prepared already by the manufacturer.

A combination pack according to the invention consists in a preferred embodiment of the invention of a first and a second drug pack with substantially the same construction. In a such combination pack the second drug pack is preferably rotated one half revolution, in the plane thereof, in relation to the first drug pack, with which it is assembled. This embodiment also enables a simple and effective arrangement of attachment means, where each card is provided with pairs of one hole and one blister placed close to each other in such way that after rotation of one pack one half revolution, each blister will be located in register above or below a hole into which it can be pressed and locked.

A method for treatment of disease is a further aspect of the invention. Thereby drugs are prescribed or administered to patients from a combination pack as above. Preferably there is thereby prescribed or administered two different drugs suitable for combination treatment of  
5 patients, which two drugs are each in one pack making part of a combination pack.

It is within the scope of the invention to design a drug pack which has blisters and/or dosage units corresponding only to certain of the holes in another drug pack with which it may be assembled. Thereby there may  
10 be achieved alternating treatment with one or more drugs depending on the therapeutic need. It is also within the scope of the invention for the blisters in one and the same card to contain dosage units of different drugs or different amounts of drugs.  
15

The invention is further described below with reference to the enclosed drawings where

Fig. 1 is a view from above of a drug pack according to one embodiment  
20 of the invention,

Fig. 2 is a view from below of the pack in Fig. 1,

Fig. 3 is a view from above of a combination pack made up by two packs  
25 as shown in Figs. 1 and 2,

Fig. 4 is a view from above of two packs according to the invention that  
may be assembled,

30 Fig. 5 is a view from above of a further drug pack according to the invention,

Fig. 6 is a view from below of the pack in Fig. 5, and

35 Fig. 7 shows a pack according to a further embodiment of the invention.

In Figs. 1-3 there is denoted with 1 a (first) drug pack comprising a card 1 of transparent plastic material having an approximate thickness of 0.25 mm, which card has, through vacuum molding, been provided on the upper side thereof with eight blisters 3 disposed in two columns in the length direction of the card. A breakable underfoil 4 consisting of aluminium having the approximate thickness of 20 µm is attached to the lower side of the card through heat sealing against the plastic material of the card. The underfoil covers at 4a the lower side of the blisters 3 in each of which is placed a tablet 5 of a drug provided with the denotation A on the tablet (drug A). Thus far described the pack 1 is in accordance with a conventional blister pack for drugs. Close to each of the blisters, the card and the underfoil has eight openings 6 of such size and shape that a blister resembling blisters 3 can be introduced therethrough. The card 2 further has six tiny circular blisters 7 which are not covered by the underfoil and which is shaped to provide a snap lock with similar blisters on a second card.

A such second card 8 has an appearance identical to the appearance of card 2 and is shown in Fig. 3 rotated one half revolution in relation to the first card 2, with which it is subsequently assembled. The card 8 has eight blisters 9 which extend up through the openings 6 in card 2. Further, card 2 has an underfoil 10 and, not visible in Fig. 3, eight openings 11 through the card and the underfoil, said openings in register with each of blisters 3. In blisters 9 is placed each one tablet 12 of a drug denoted B on the tablet (drug B). Thus; dosage units of drug A and drug B are located in the combination pack adjacent to each other in pairs.

In Fig. 4 there is illustrated that a first drug pack 13 has three blisters 15 for a drug, said pack being assemblable with a second drug pack 14 having six blisters 16 for a drug arranged in pairs. The pack 13 has three holes 17 each corresponding to two blisters 16 arranged in pairs, while pack 14 has three holes 18 corresponding to each of blisters 15.

35

In Figs. 5 and 6 is illustrated that a pack, which is mainly in accordance with the pack 1 in Fig. 1, has no snap locks and has instead

three strips 22 of adhesive material provided with a protective sheet 21. Before assembling of two packs to one combination pack the protective sheet 21 is removed from the pack that will be placed above, and the adhesive material is brought to adhere to the upper side of the other pack.

With 23 is denoted a frame printed around one blister and one hole, said frame provided with a digital denotation and indicating a combination dosage to be taken on one and the same occasion. The digital denotation may in a known manner be replaced with other denotation such as e.g. "morning", "evening" and/or day of the week.

The pack shown in Fig. 7 corresponds in general to the pack in Fig. 1 and is thus designed to be assemblable with a similar pack. The pack is however modified thus that the attachment means are designed as pairs of one blister 24 and one hole 25 where each blister 24 in one of the packs will be in register below, and on assembling will be locked into a hole 25 in the other pack. Alternatively, in a pack in accordance with Figs. 1-3, the blisters 3 for receiving dosage units in a first pack 1 be shaped to be locked into corresponding holes 11 in a second pack.

As illustrative and by no means limiting examples of drugs which may be suggested for supply in a pack according to the invention, there may be mentioned:

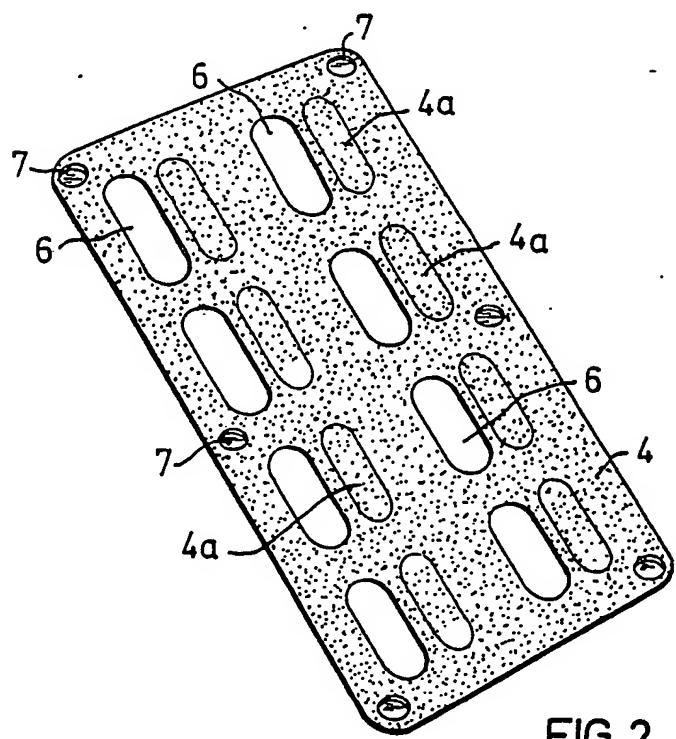
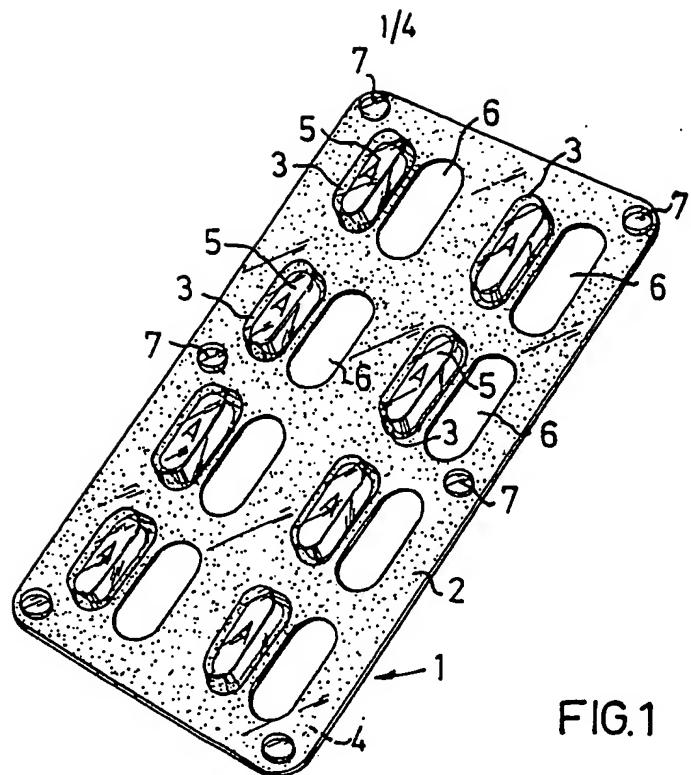
25

	<u>Drug A</u>	<u>Drug B</u>
	paracetamol	oxazepam
	paracetamol + codeine	oxazepam
30	paracetamol + codeine	ibuprofen
	codeine	ibuprofen
	dextropropoxyphene	diflunisal
	metoprolol	furosemide
	atenolol	furosemide
35	metoprolol	felodipine
	metoprolol + furosemide	felodipine

CLAIMS

1. A drug pack (1) comprising a first card (2) which on the upper side thereof is provided with a number of blisters (3) for receiving therein  
5 drug dosage units, such as tablets (5) or capsules, and which on the lower side thereof has a breakable underfoil (4) attached thereto, through which dosage units may be released, characterized in that the first card has a number of openings (6) arranged thus that blisters (9) belonging to a second drug pack may be introduced through the openings  
10 from the lower side of the first card to the formation of a combination pack, wherein the second drug pack comprises a second card (8) provided with such blisters (9), openings (11) corresponding to the blisters of the first card and a second underfoil (10).
- 15 2. A drug pack according to claim 1, characterized in that the openings (6) extend also through the underfoil (4).
- 20 3. A drug pack according to claim 1 or 2, characterized in that each opening (4) in the first card (2) is located at a shorter distance from one blister (3) than from other blisters in said first card.
- 25 4. A drug pack according to one or more of the preceding claims, characterized in that attachment means are arranged for attaching the first card to the second card.
- 30 5. A drug pack according to one or more of the preceding claims characterized in the attachment means comprise snap locks (7).
- 35 6. A drug pack according to one or more of the preceding claims, characterized in the attachment means comprise adhesive material (22) which is coated on or which on assembling is brought into contact with the underfoil of the first card.
7. A combination pack for drugs, characterized in that it comprises a first (1) and a second drug pack, defined in one or more of the preceding claims, assembled to each other.

8. A combination pack for drugs according to claim 7, characterized in that the first and the second drug pack has substantially the same construction.
- 5     9. A combination pack according to claim 8, characterized in that the first drug pack is assembled with the second drug pack, which is rotated one half revolution in the plane thereof in relation to the first pack.
- 10    10. A combination pack according to claim 7, characterized in that the first and the second drug pack has different construction between themselves.
- 15    11. Use of a pack according to one or more of claims 1-6 for preparing a pack for two or more drugs.
12. Use of a pack according to one or more of claims 1-6 for providing two or more drugs to a patient.
- 20    13. A method for treatment of disease characterized in that drugs are prescribed and/or administered to a patient from a combination pack defined in one or more of claims 7 to 10.
- 25    14. A method for treatment according to claim 11, characterized in that there is prescribed and/or administered to the patient two different drugs suitable for combination treatment of the patient, which two drugs are each in one pack making part of the combination pack.



2/4

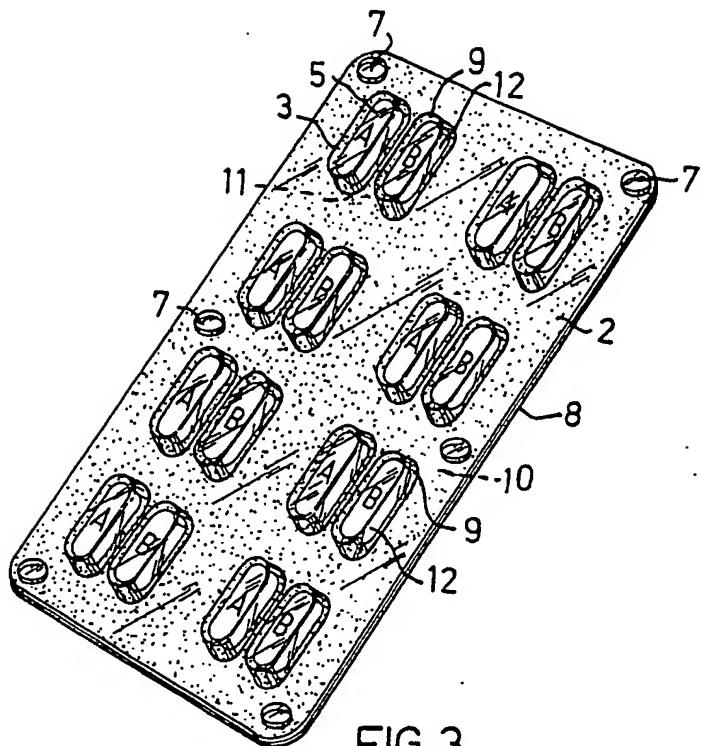


FIG. 3

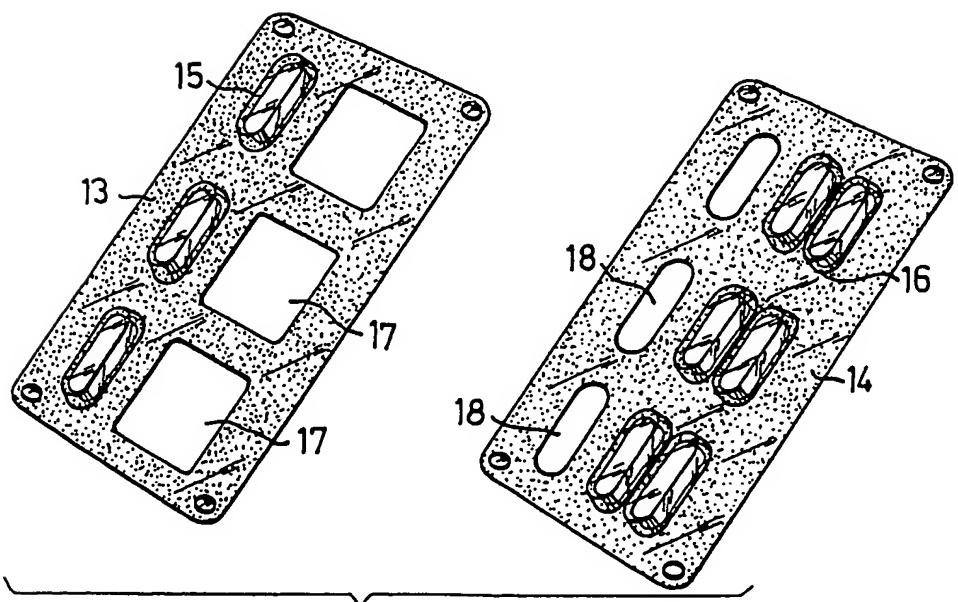
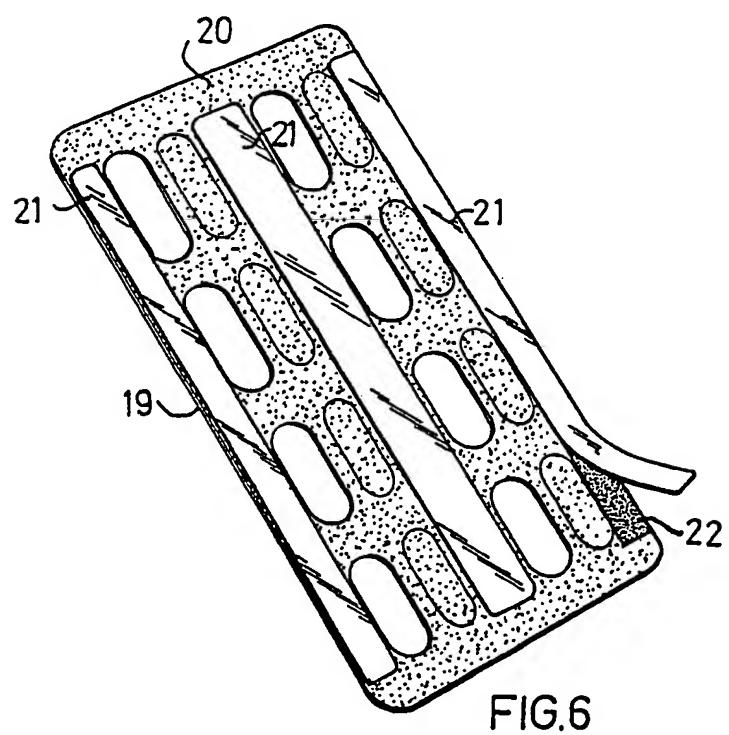
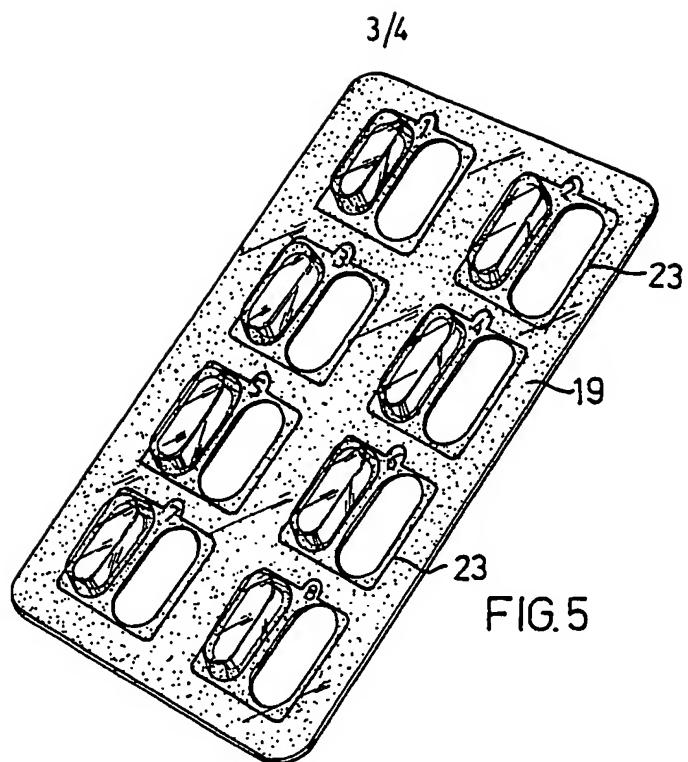


FIG. 4



4/4

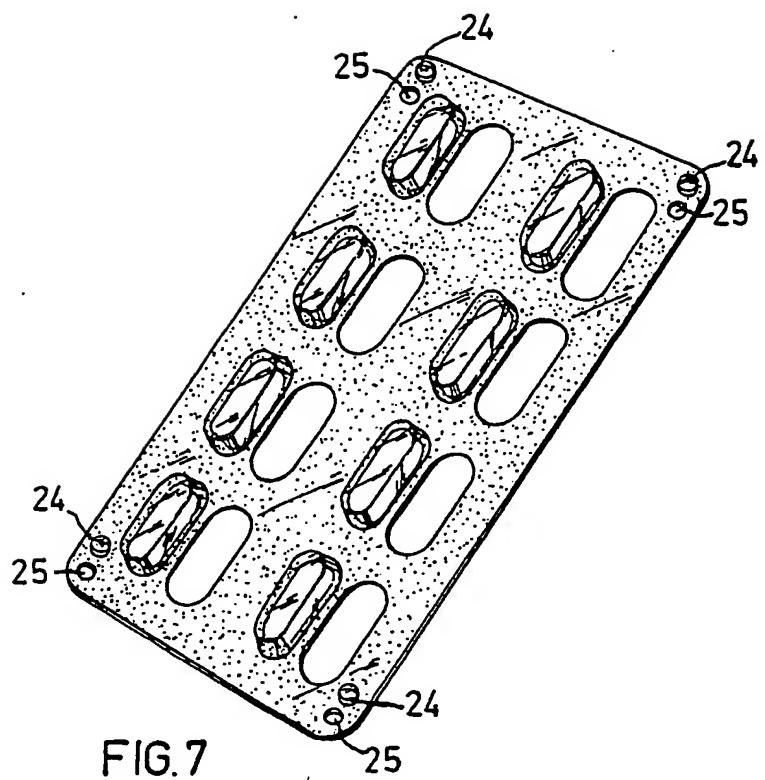


FIG. 7

# INTERNATIONAL SEARCH REPORT

International Application No PCT/SE87/00430

## I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) \*

According to International Patent Classification (IPC) or to both National Classification and IPC 4

B 65 D 85/56

## II. FIELDS SEARCHED

Minimum Documentation Searched 7

Classification System	Classification Symbols
IPC 4	A 61 J 1/00; B 65 D 73/00, /02, 75/22, /24, /32-/38, /52, 83/04, 85/56, /62
Nat Cl	81c: 27 .../...

Documentation Searched other than Minimum Documentation  
to the Extent that such Documents are Included in the Fields Searched 8

SE, NO, DK, FI classes as above

## III. DOCUMENTS CONSIDERED TO BE RELEVANT\*

Category *	Citation of Document, 11 with indication, where appropriate, of the relevant passages 12	Relevant to Claim No. 13
Y	DE, A1, 3 139 403 (KLOCKE HARTMUT) 14 April 1983	1-6
Y	US, A, 4 254 871 (POORE) 10 March 1981 & LU, 81321 BE, 876615 NL, 7904013 FR, 2427273 DE, 2920162 GB, 1601885 US, 4362000 SE, 7904684 CH, 642026	1-6
A	GB, A, 1 381 218 (PACO PACKAGING, INC) 22 January 1975	1
A	CH, A5, 346 819 (IVERS-LEE COMPANY) 15 July 1960	1

\* Special categories of cited documents: 10

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the International filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the International filing date but later than the priority date claimed

"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

## IV. CERTIFICATION

Date of the Actual Completion of the International Search

1987-11-30

Date of Mailing of this International Search Report

1987-12-11

International Searching Authority

Swedish Patent Office

Signature of Authorized Officer

Helena Åkerlund  
Helena Åkerlund

## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

II

Fields Searched (cont)

US Cl    206: 303, 459, 528-540;  
221: 25, 26, 64, 87-89, 92, 199, 302, 312

V.  OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE<sup>1</sup>

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1.  Claim numbers 13-14, because they relate to subject matter not required to be searched by this Authority, namely:

according to PL § 1

2.  Claim numbers ....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3.  Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI.  OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING<sup>2</sup>

This International Searching Authority found multiple inventions in this International application as follows:

1.  As all required additional search fees were timely paid by the applicant, this International search report covers all searchable claims of the International application.

2.  As only some of the required additional search fees were timely paid by the applicant, this International search report covers only those claims of the International application for which fees were paid, specifically claims:

3.  No required additional search fees were timely paid by the applicant. Consequently, this International search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4.  As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

## Remark on Protest

- The additional search fees were accompanied by applicant's protest.
- No protest accompanied the payment of additional search fees.